

Applicants : Lorna W. Role et al.  
U.S. Serial No.: 09/312,596  
Filed : May 14, 1999  
Page 4

REMARKS

Claims 1-19 and 25-34 are pending in the subject application. Claims 1-19 and 25-29 have been canceled without prejudice as withdrawn from consideration. Claim 30 has been amended in order to introduce certain formatting changes. Applicants maintain that the amendments to claim 30 do not introduce an issue of new matter. Accordingly, claims 30-34 will be pending and under examination in the subject application upon entry of this Amendment.

Applicants respectfully request that, in view of the remarks made herein, the Examiner withdraw the outstanding rejections.

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 30-34 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner asserts that the skilled artisan cannot make or use the broad genus of "nARIA polypeptide."

In response, applicants respectfully traverse the rejection.

Briefly, claims 30-34 as amended provide a method for determining whether an agent is capable of modulating the binding of a nARIA polypeptide having the sequence identified as SEQ ID NO:4 to a receptor selected from the group consisting of

Applicants : Lorna W. Role et al.  
U.S. Serial No.: 09/312,596  
Filed : May 14, 1999  
Page 5

erbB2, erbB3 and erbB4.

Applicants stress that claims 30-34 identify the nARIA polypeptide by a specific SEQ ID No. set forth in the subject application, and maintain that the instant method is enabled.

The Examiner also rejected claims 30-34 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In response, applicants respectfully traverse the rejection. Applicants' traversal is based on the reasons set forth above in connection with the Examiner's enablement rejection.

In view of the above remarks, applicants maintain that claims 30-34 satisfy the requirements of 35 U.S.C. §112, first paragraph.

#### **Rejection Under 35 U.S.C. §112, Second Paragraph**

The Examiner rejected claims 30-34 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Applicants : Lorna W. Role et al.  
U.S. Serial No.: 09/312,596  
Filed : May 14, 1999  
Page 6

In support of the rejection, the Examiner states that "[i]t is vague and unclear how 'the agent' is supposed to be used in base claim [30] when it is recited as being absent in both steps (a) and (c)."

In response, applicants respectfully traverse the rejection.

Applicants note that claim 30, as amended, does not contain the language objected to by the Examiner.

In view of the above remarks, applicants maintain that claims 30-34 satisfy the requirements of 35 U.S.C. §112, second paragraph.

**Rejection Under 35 U.S.C. §102(b)**

The Examiner rejected claims 30-33 under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,602,096 to Goodearl ("Goodearl").

In response, applicants respectfully traverse the rejection.

Again, the claimed invention provides a method for determining whether an agent is capable of modulating the binding of a *nARIA polypeptide* having the sequence identified as SEQ ID. NO:4 to a receptor selected from the group consisting of erbB2, erbB3 and erbB4. Contrary to the Examiner's position, this method requires, in relevant part, contacting the *nARIA polypeptide* with the receptor in the presence of the agent. For a reference to anticipate the instant invention, it would have to teach all the

Applicants : Lorna W. Role et al.  
U.S. Serial No.: 09/312,596  
Filed : May 14, 1999  
Page 7

*elements thereof.*

Clearly, Goodearl fails to do this, and the Examiner has not shown otherwise. According to the Examiner, Goodearl teaches glial growth factors (GGF) that "possess nARIA activity" and competitive assays with GGF and antibodies. Goodearl fails to teach a nARIA polypeptide or any assay involving a nARIA polypeptide. It is irrelevant that, according to the Examiner, GGF posses nARIA activity. Claims 30-33 do not recite GGF but instead recite nARIA polypeptide, and one having a specific sequence at that. As noted in applicants' February 19, 2003 Communication, the Examiner has not provided any teaching that suggests that GGF is the same as nARIA polypeptide. Applicants maintain that Goodearl fails to anticipate the instant invention, because it does not teach each and every element of the claimed method.

Finally, applicants note the Examiner's assertion that the claims as presently written do not require the presence of an agent. Applicants disagree with the Examiner and point out that the rejected claims provide for, in relevant part, contacting the nARIA polypeptide with an agent. Applicants direct the Examiner's attention to step (a) of claim 30 for an example of this language.

In view of the above remarks, applicants maintain that claims 30-33 satisfy the requirements of 35 U.S.C. §102(b).

Applicants : Lorna W. Role et al.  
U.S. Serial No.: 09/312,596  
Filed : May 14, 1999  
Page 8

**Rejection Under 35 U.S.C. §102(e)**

The Examiner rejected claims 30-34 under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 6,284,535 B1 ("Role").

In response, applicants respectfully traverse the rejection.

Claims 30-34 are discussed above, as is the standard for anticipation.

As with Goodearl, Role fails to teach each and every element of the claimed method. Specifically, as applicants noted in their February 19, 2003 Communication and August 27, 2002 Amendment, nowhere does Role disclose "contacting the nARIA polypeptide to a receptor selected from the group consisting of erbB2, erbB3 and erbB4, under conditions permitting the binding of the nARIA polypeptide to the receptor in the absence of the agent." The Examiner has not responded to the arguments set forth in applicants' February 19, 2003 Communication and August 27, 2002 Amendment, indicating how Role anticipates the instant invention by providing the above-described disclosure.

Finally, applicants again note the Examiner's assertion that the claims as presently written do not require the presence of an agent. Applicants disagree with this assertion for the reason set forth above.

In view of the above remarks, applicants maintain that claims 30-34 satisfy the requirements of 35 U.S.C. §102(e).

Applicants : Lorna W. Role et al.  
U.S. Serial No.: 09/312,596  
Filed : May 14, 1999  
Page 9

**Rejection Under 35 U.S.C. §102(f)**

The Examiner rejected claims 30-34 under 35 U.S.C. §102(f) as allegedly derived from U.S. Patent No. 6,284,535 B1.

In response, applicants respectfully traverse the rejection.

Claims 30-34 are discussed above.

In response to the Examiner's rejection, applicants again point out that nowhere does Role recite "contacting the nARIA polypeptide with the agent and a receptor selected from the group consisting of erbB2, erbB3 and erbB4, under conditions permitting the binding of the nARIA polypeptide to the receptor." Rather, this subject matter and the claimed method comprising it, disclosed only in the instant application, are the invention of the three named applicants. Thus, the Examiner's assertion of derivation is without merit.

Applicants maintain that, for the reasons stated above, claims 30-34 satisfy the requirements of 35 U.S.C. §102(f).

**Rejection Under 35 U.S.C. §103(a)**

The Examiner rejected claims 30-34 under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 5,602,096 to Goodearl et al. ("Goodearl") in view of U.S. Patent No. 6,284,535 B1. Applicants' acknowledge the Examiner's comments regarding the August 27, 2002 Amendment.

Applicants : Lorna W. Role et al.

U.S. Serial No.: 09/312,596

Filed : May 14, 1999

Page 10

In response, applicants respectfully traverse the rejection. Applicants maintain that the Examiner has failed to establish a *prima facie* case of obviousness.

To establish a *prima facie* case of obviousness, the Examiner must demonstrate three things with respect to each claim. First, the cited references, when combined, teach or suggest every element of the claim. Second, one of ordinary skill would have been motivated to combine the teachings of the cited references at the time of the invention. And third, there would have been a reasonable expectation that the claimed invention would succeed.

Applicants maintain that the cited references fail to support a *prima facie* case of obviousness of claims 30-34.

The rejected claims provide methods for determining whether an agent is capable of modulating the binding of a nARIA polypeptide to a receptor selected from erbB2, erbB3 and erbB4. The cited references are discussed above.

Applicants maintain that the cited references, when combined, do not teach or suggest every element of the claims. Specifically, nowhere does either reference teach the binding of a nARIA polypeptide to an erbB2, erbB3 and erbB4 receptor in the presence of an agent to be tested. The Examiner alleges that such teachings are made by the references, but has not specifically cited where such teachings are made. Given that Goodearl and Role combined do not teach all the elements of claims 30-34, it follows that these references also fail to

Applicants : Lorna W. Role et al.

U.S. Serial No.: 09/312,596

Filed : May 14, 1999

Page 11

create a motive to combine or a reasonable expectation of success.

In view of the above remarks, applicants maintain that the Examiner has failed to set forth a *prima facie* case of obviousness, and that accordingly, claims 30-34 satisfy the requirements of 35 U.S.C. §103(a).

**Conclusion**

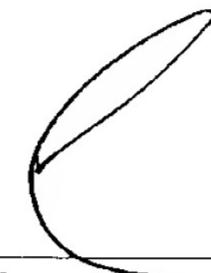
Applicants maintain that claims 30-34 are in condition for allowance, and thus, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

Applicants : Lorna W. Role et al.  
U.S. Serial No.: 09/312,596  
Filed : May 14, 1999  
Page 12

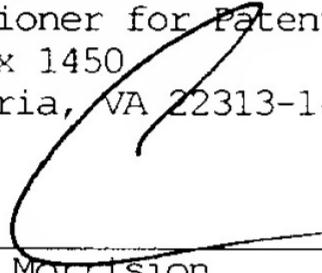
No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White  
Registration No. 28,678  
Alan J. Morrison  
Registration No. 37,399  
Attorneys for Applicants  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, New York 10036  
(212) 278-0400

I hereby certify that this paper is being deposited this date with the U.S. Postal Service as first class mail addressed to:  
Mail Stop After Final  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

  
Date 9/10/03

Alan J. Morrison  
Registration No. 37,399